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8 UNITED STATES DISTRICT COURT

9 DISTRICT OF ARIZONA

10 In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

11 **PLAINTIFF'S RESPONSE IN**
12 **OPPOSITION TO DEFENDANTS'**
13 **MOTION TO EXCLUDE THE**
14 **OPINIONS OF SUZANNE PARISIAN,**
M.D.

15
16 Plaintiffs respond in opposition to Defendants' Motion to Exclude the Opinions of
17 Suzanne Parisian, M.D. [Doc. 7308]. Plaintiffs incorporate in this response their
18 Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's
19 Motions to Exclude Plaintiffs' Experts under Rule 702 and *Daubert* ("Omnibus Mem.")
20 [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in
21 the Omnibus Memorandum, this Court should deny the Motion.

22 **I. INTRODUCTION**

23 Dr. Parisian is a qualified expert whose testimony on FDA regulatory matters has
24 been found helpful by courts and admitted in many cases. Her opinions in this case are
25 within her expertise and are not only admissible but necessary to give the jury a clear and
26 concise understanding of the regulatory history of Bard's IVC filters and how it failed its
27 obligations to the public to design, test, and market reasonably safe medical devices.
28

1 Bard's attacks on Dr. Parisian based on the handful of unfavorable rulings against
 2 her fail because those rulings involved different reports addressing different devices,
 3 drugs, and litigations. Those few rulings contrast with the many others—including in this
 4 very litigation—finding her testimony helpful and admissible. Bard offers very few actual
 5 examples from Dr. Parisian's reports in *this* case of purportedly improper testimony, and
 6 even those examples fail to establish grounds for excluding any of her opinions.

7 The rest of Bard's attacks on Dr. Parisian—that she has a history of work as a
 8 plaintiff's expert, that she didn't look at enough documents, that she's an advocate—are
 9 arguments for Bard's closing statement to the jury or lines of inquiry in cross-
 10 examination. They are not grounds for exclusion under Rule 702. Dr. Parisian is
 11 eminently qualified to render opinions on FDA regulatory matters based on her decades of
 12 experience working with medical devices, and Bard's motion should be denied in full.

13 **II. DR. PARISIAN'S QUALIFICATIONS**

14 Dr. Parisian is a licensed medical doctor in the State of Arizona, a board-certified
 15 Anatomic and Clinical Pathologist, and an FDA regulatory expert. From 1991 to 1995,
 16 she was a commissioned officer in the United States Public Health Service—achieving
 17 final rank of Lieutenant Commander—assigned to the FDA. Exhibit 1 hereto, Declaration
 18 of Suzanne Parisian, M.D., ¶ 2.¹ . At the FDA, she worked in the Center for Devices and
 19 Radiological Health (“CDRH”). *Id.* ¶ 3. Part of her duties at CDRH was to provide
 20 medical and then regulatory support for both pre-market and post-market issues. *Id.* ¶ 4.

21 From 1991-1993 Dr. Parisian was a member of the Office of Health Affairs
 22 (“OHA”), a division of the FDA, as one of several clinicians. *Id.* ¶ 5. As part of her job
 23 providing regulatory support to both the Office of Compliance and Office of Device
 24 Evaluation at the FDA, her responsibilities at OHA included health hazard and health risk
 25 assessment; FDA Safety Alerts; physician and layperson communications; forensic review
 26 of patient deaths with medical devices; review of adverse event reports and medical

27 ¹ Dr. Parisian's background is also described in detail in her March 3, 2017, Rule 26
 28 report and her Curriculum Vitae, Appendix A thereto. These can be found at Exhibit A to
 Bard's motion.

1 literature to identify safety trends; supporting the Office of General Counsel for
2 mandatory recalls including reviewing internal corporate and manufacturing records to
3 ensure compliance with the FDCA; and the review of product labeling, promotions,
4 advertising, and corporate records to ensure compliance with the Food, Drug and
5 Cosmetic Act (“FDCA”). *Id.* ¶ 6. In this function, she was required to become familiar
6 with the FDCA and its implementing regulations for all products under FDA oversight.
7 *Id.* ¶ 7. She was also assigned to participate directly with industry groups, professional
8 groups, and other government agencies as an official representative of the FDA. *Id.* ¶ 8.

9 In 1993, CDRH was re-organized by the FDA Commissioner. *Id.* ¶ 9. OHA was
10 disbanded, and clinical staff including Dr. Parisian were assigned to the Office of Device
11 Evaluation (“ODE”) with an increased emphasis on pre-market review of new products.
12 *Id.* ¶ 10. During this transition period at CDRH she continued her post-market OHA
13 functions including procedures for health risk assessments and health hazards evaluations
14 pursuant to 21 C.F.R. Part 7. *Id.* ¶ 11. She was promoted to be one of two ODE Chief
15 Medical Officers, and in that capacity Dr. Parisian trained medical officers and scientific
16 reviewers on the agency’s regulations and oversaw all pre-market review processes
17 including 510(k)s (21 C.F.R. § 807), Pre-market Approval Applications (21 C.F.R. § 814)
18 and Investigational New Device Applications (21 C.F.R. § 812). *Id.* ¶ 12. In conducting
19 and training others on these review processes Dr. Parisian was involved with
20 consideration of a manufacturer’s proposed design and feasibility studies; evaluated
21 clinical trials, patient data, patient protections, proposed labeling, medical and scientific
22 literature, annual report requirements, and medical device reporting; and interacted with
23 industry, scientists, healthcare providers, and patient groups. *Id.* ¶ 13. She reviewed
24 proposed clinical trials and pre-marketing applications for medical devices and, as a
25 pathologist, reviewed pre-clinical and animal toxicology and biocompatibility data to
26 propose methods to industry for product safety testing. *Id.* ¶ 14. Dr. Parisian was one of
27 the first instructors at CDRH’s new staff college, training FDA clinical reviewers on the
28

1 FDA's requirements as well as issues to consider in the evaluation of clinical data
2 provided in industry's investigational and pre-marketing applications. *Id.* ¶ 15.

3 Dr. Parisian's responsibilities at FDA also included the review of both mandatory
4 and voluntary adverse event reports submitted to the FDA by health care providers,
5 patients, and others to identify safety trends occurring in FDA-regulated products. *Id.* ¶
6 16. In OHA she presided over 162 health risk assessments and with ODE an additional
7 100 assessments. *Id.* ¶ 17. She advised others on public health risk issues and made
8 recommendations based on her training and experience regarding regulatory actions that
9 should be undertaken by stakeholders to help protect the public welfare. *Id.* ¶ 18.

10 Dr. Parisian received her Medical Doctorate from the University of South Florida
11 and is currently licensed as a physician in Arizona. *Id.* ¶ 19. She has clinical patient-care
12 experience and since 1989 has been board-certified in Anatomic and Clinical Pathology.
13 *Id.* ¶ 20. She also holds a Master's Degree in Biology from the University of Central
14 Florida. *Id.* ¶ 21. Prior to starting her work at the FDA, she was a practicing physician
15 treating patients in various clinical settings and a practicing pathologist. *Id.* ¶ 22. In
16 addition to her regulatory duties at the FDA, Dr. Parisian also worked as a clinician one
17 half-day per week at the Armed Forces Institute of Pathology's Office of the Medical
18 Examiner for the Armed Forces in Washington, D.C. *Id.*

19 Dr. Parisian has over 26 years of experience in FDA regulations and products
20 regulated by FDA including the development, manufacture, monitoring, and marketing of
21 medical devices. *Id.* ¶ 23. Both as a medical officer at the FDA and with her FDA
22 Regulatory consulting business since 1995, Dr. Parisian has remained actively engaged in
23 FDA regulatory issues including the oversight of medical devices. *Id.* ¶ 24. Throughout
24 her career and using the methodology acquired during her work for the FDA she has
25 reviewed hundreds of pre-market applications for medical devices. *Id.* ¶ 25. As an FDA
26 regulatory expert, she has been directly involved with industry, including product design
27 and production, creation of submissions to obtain approval or clearance from the FDA,
28 and safety issues. *Id.* ¶ 26. As a medical and regulatory expert Dr. Parisian has been

1 required, whether for FDA, litigation, or industry support, to review the regulatory
2 history, testing, and clinical data for drugs and medical devices as described by the
3 manufacturer in marketing applications and communications to and with the FDA and the
4 public, including draft and final labeling. *Id.* ¶ 27.

5 After leaving the FDA in 1995, Dr. Parisian relocated to Phoenix, Arizona in 2004,
6 where she continued to be a guest lecturer and consultant to individuals, professional and
7 patient groups, students, industry, and law firms regarding FDA regulations and oversight
8 of products. *Id.* ¶ 28. She is a member of the Maricopa County Medical Society, the
9 Arizona Medical Association, and the Arizona BioIndustry Association. *Id.* ¶ 29. Her
10 consultation work includes remaining up-to-date with changes occurring at the FDA
11 including issuance of Guidances, Safety Alerts, Recalls, enforcement actions, special
12 reports, public working groups, and reclassification of devices. *Id.* ¶ 30. She also
13 maintains awareness of changes in the FDA's authority from Congress through
14 amendments to the FDCA and the impact of those amendments on devices, biologics, and
15 drugs. *Id.* ¶ 31.

16 Dr. Parisian has over 39 years of medical experience including 26 years of hands-
17 on experience with FDA regulatory issues, public safety, and medical devices pre-market
18 clearance and approval processes. *Id.* ¶ 32. In 2001, Dr. Parisian published a textbook,
19 *FDA Inside and Out*, which is now the graduate student textbook in the Biomedical Ph.D.
20 programs at Wayne State University and Colorado State University. *Id.* ¶ 33.

21 For the past twenty years, Dr. Parisian has provided forensic regulatory litigation
22 support for both plaintiffs and defendants. *Id.* ¶ 34. As described below, her
23 methodology has routinely survived scrutiny under Rule 702 in matters involving medical
24 devices, prescription drugs, and biologics.

25 **III. DR. PARISIAN'S TESTIMONY**

26 Bard's decisions to seek regulatory clearance of its retrievable IVC filters and to
27 proceed with selling them to the public are central issues in this case. One of Bard's
28 primary defenses is that the FDA's clearance of its devices for sale under the 510(k)

1 clearance process absolves Bard of any responsibility for harm caused by its products and
2 is dispositive of the allegation that those produces are defective. This defense hinges in
3 part on creative interpretations of the FDA's regulations, processes, and terminology. The
4 FDA regulatory process, including the process for approval and clearance of medical
5 devices, involve technical matters beyond the understanding of lay people. *Placencia v. I-*
6 *Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *10 (D. Ariz. Nov. 20,
7 2012) (noting in medical device case that the "FDA regulatory process is complex and
8 beyond the experience of the average juror" and denying motion to exclude plaintiffs'
9 FDA regulatory expert). To decide whether Bard breached its duties of care, the jury will
10 need to hear from a knowledgeable expert to explain the FDA's role in regulating medical
11 devices, how those regulations apply to Bard and its IVC filters, and whether Bard
12 complied with FDA standards and its obligations as a medical device manufacturer under
13 federal law. *Id.* (noting that plaintiffs' expert's "explanations and opinions might well be
14 helpful in understanding matters that are relevant to Plaintiffs' tort claims"); *see also In re*
15 *Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 474 (E.D.N.Y. 2016) (denying
16 motion to exclude Dr. Parisian and stating that "[e]xpert testimony from a regulatory
17 expert on complicated schemes like the FDAs statutory framework, as well as opinions on
18 the adequacy of a drug's label and the reasonableness of a pharmaceutical company's
19 conduct, are useful in assisting the trier of fact").

20 Plaintiffs thus offer Dr. Parisian as their regulatory expert witness to testify
21 regarding Bard's actions and inactions in the context of its regulatory responsibilities in
22 testing and marketing its IVC filters. Specifically, she will provide testimony regarding:

- 23 • the role, procedure and function of the FDA in its oversight of medical
24 device manufacturers;
- 25 • the duties and responsibilities of Bard to obtain FDA clearance for its IVC
26 filters and to market safe and effective devices;
- 27 • the duties and responsibilities Bard has under FDA rules to protect
28 consumers of its products by both monitoring device performance

(including proper studies and follow-up on reported complications) and communicating the risks attendant to the use of its devices to the public and to physicians;

- the complete process by which manufacturers apply for, document, and obtain regulatory clearance for devices such as IVC filters;
- Bard's continuing duty to maintain expertise about its product and investigate risks related to its product;
- the adequacy of Bard's pre- and post-market study, design, testing, validation and monitoring of its retrievable IVC filters starting with the Recovery Filter; and
- Bard's specific failures to comply with its duties under FDA regulations.

IV. ARGUMENT

Central to Bard's liability in this case is its decision to market and sell its IVC filters. Its defense hinges in part on its creative interpretations of FDA regulations and terminology. Plaintiff has disclosed Dr. Parisian as a regulatory expert to address these issues. Dr. Parisian is extraordinarily well qualified and knowledgeable in this area and has been admitted to testify in this capacity dozens if not hundreds of times by a plethora of courts all over the country.

Nevertheless, Bard seeks to exclude her testimony, claiming Dr. Parisian lacks the qualification to express opinions on FDA matters, is too biased in favor of plaintiffs, uses an inappropriate methodology, and lacks a reliable foundation her opinions. Specifically, Bard mischaracterizes Dr. Parisian's experience and her role as an expert, distorts previous rulings on the admissibility of her testimony to misleadingly suggest that she has been routinely excluded when in fact the opposite is true, and claims that her opinions are both speculative and advocacy.

In fact, Dr. Parisian's testimony is soundly derived from her professional experience, her knowledge of FDA regulations and processes for reviewing medical devices, and her review of the Bard documents describing the regulatory history of its

1 IVC filters. That Dr. Parisian's opinions are unfavorable to Bard does not reduce her
 2 testimony to "advocacy" nor render it unreliable. There is no basis for excluding her or
 3 any of her opinions, and Bard's motion should be denied in full.

4 **A. A Handful of Older Rulings Excluding Dr. Parisian's Reports and**
 5 **Opinions Have No Relevance to the Admissibility of Her Reports and**
 6 **Opinions in This Case.**

7 Bard misleadingly cites to a handful of cases, all of which are at least five years
 8 old, where Dr. Parisian's opinions were limited, often only in part, to support sweeping
 9 and generalized arguments that *all* of her opinions should be excluded. These other
 10 rulings—involving different products, factual circumstances, and expert reports from
 11 those at issue here—have minimal relevance to the Court's Rule 702 analysis of her
 12 opinions. In fact, Dr. Parisian is not only routinely admitted to testify on FDA matters in
 13 state and federal courts around the country, Bard's same motion to exclude her has
 14 previously been denied in this litigation. In *Phillips v. C.R. Bard, Inc.*, 3:12-CV-00344-
 15 RCJ, 2014 WL 7177256 (D. Nev. Dec. 16, 2014), a pre-MDL IVC filter case with which
 16 the Court is by now familiar, the Nevada district court found Dr. Parisian's opinions
 17 relevant and reliable concerning the FDA regulatory scheme for medical devices, the
 18 510(k) clearance process, Bard's actions within that process, its testing and post-market
 19 safety studies of its IVC filters, and Bard's labeling. *Id.* at **4-5.

20 Notably, the *Phillips* court denied Bard's motion attacking Dr. Parisian's
 21 methodology based on her same description of her methodology from the same deposition
 22 that Bard cites to the Court now. *See* Exhibit 2, June 13, 2014, Deposition of Suzanne
 23 Parisian, at 2, 7:24-8:6 (statement from defense counsel that deposition was noticed in
 24 *Phillips* as well as two other Bard cases); *cf.* Defendants' Exhibit D (Bard's excerpts from
 25 same deposition). The *Phillips* court found that any concerns about ambiguity or
 26 vagueness in Dr. Parisian's methodology were due to her potentially at the time of that
 27 deposition being called as a design or testing expert, and that as to FDA issues—the area
 28 she ultimately testified about in *Phillips* and the area she will testify about in this

litigation—Dr. Parisian’s methodology could be challenged in cross-examination at trial but was not a basis for exclusion:

As to the areas in which the Court is likely to admit Dr. Parisian, i.e., governmental regulations and perhaps the appropriateness of testing as to a given device, no detailed scientific methods would be expected. The Court will permit her to explain her methods of comparing Defendants’ actions to FDA regulations and industry testing standards at trial

Id. at *5. Thus the exact same opinions Bard seeks to exclude—for the exact same reasons based on the exact same evidence—have already been found to be admissible in this litigation.

Bard conspicuously avoids mentioning *Phillips* because it is dispositive of its motion. It also avoids mentioning all of the other decisions that have rejected Bard’s arguments. Besides *Phillips*, the following recent cases have addressed Dr. Parisian’s qualifications, methodology, and opinions and found that she is qualified as an expert to testify on the FDA and regulatory issues Plaintiffs will offer her for in this litigation:

- *In re Xarelto (Rivaroxaban) Products Liability Litigation*, MDL 2592, 2017 WL 1352860, at *3 (E.D. La. Apr. 13, 2017), motion attacking Dr. Parisian’s recitation of regulatory history as improper and also arguing that she was unqualified and used unreliable methodology denied in full. The court held that Dr. Parisian was qualified and used sound methodology. It also noted, of equal applicability to Bard’s motion, that the “thrust of the Defendants’ objections seems to be that they are concerned the witness may assume an advocate role at trial. If Dr. Parisian assumes an advocate role at trial, the Court will address it at that time.”
- *Jones v. Novartis Pharm. Corp.*, 235 F. Supp. 3d 1244, 1253-65 (N.D. Ala. 2017), motion to exclude denied. The court granted the motion as to opinions on intent, causation, “notice,” and similar matters, but otherwise found Dr. Parisian was an admissible expert. The court acknowledged and distinguished the same negative case law cited by Bard and found that Dr. Parisian was well-qualified, she followed an appropriate methodology, and her opinions were appropriate and relevant.

- 1 • *In re Ethicon Inc. Pelvic Repair Systems Products Liability Litigation*, MDL 2327,
2 2016 WL 4608165, at *3 (S.D.W. Va., Sept. 2, 2016), motion attacking Dr.
3 Parisian’s expert testimony about the warnings and labeling of transvaginal mesh
4 products and arguing that her testimony was not reliable denied. The court found
5 that Dr. Parisian was qualified to testify about product warnings because in “her
6 career, Dr. Parisian helped create IFUs and provided comments for patient
7 brochures. During her time with the FDA and as a consultant, she has reviewed
8 proposed labeling. She also has more than twenty-four years of experience with
9 research and development of medical devices and pharmaceuticals.”
- 10 • *In re Mirena*, 169 F. Supp. 3d at 478-82, motion denied as “to using documents
11 and background to opine on the FDA, the adequacy of Mirena’s label and the
12 reasonableness of Bayer’s conduct pursuant to FDA regulations.” Narrative trial
13 testimony merely regurgitating facts and documents would not be allowed but “Dr.
14 Parisian’s experience as an officer at the FDA qualifies her to opine on the
15 background of the FDA, its functions, and the FDA’s regulatory framework.” The
16 court went through several aspects of her opinions and found that her testimony
17 regarding “the complex FDA regulatory framework, Bayer’s compliance with FDA
18 regulations, and the adequacy of the Mirena label are relevant to this case and
19 would be helpful to a jury.”
- 20 • *Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1045-1047 (D. Minn. 2013),
21 denying motion to exclude, among other things, testimony regarding what
22 defendant pain pump manufacturer “should have known. As stated above, the issue
23 of what Woo Young should have known is relevant to Block’s failure to warn
24 claim.” The Court therefore allowed Dr. Parisian “to testify to the state of the
25 medical literature, the state of FDA approval, and other information about which
26 Woo Young should have been aware” based on her expertise “as a medical doctor
27 who formerly worked for the FDA. Any challenges to Dr. Parisian's expertise on
28 these topics can be addressed on cross examination.” Further, the court allowed

1 Dr. Parisian “to testify to the general nature of the FDA’s approval and regulatory
 2 process, the FDA’s general expectations with respect to testing and marketing of
 3 new products, and Woo Young’s actions in that respect, to the extent supported by
 4 the record evidence.”

- 5 • *Bartoli v. Novartis Pharma. Corp.*, 3:13-cv-0724, 2014 WL 1515870, at *6 (M.D.
 6 Pa., Apr. 17, 2014), and *Forman v. Novartis Pharma. Corp.*, 794 F. Supp. 2d 382,
 7 384 (E.D.N.Y.2011), both found that “Dr. Parisian was qualified to testify as to
 8 FDA regulatory scheme, role of the FDA and interactions with pharmaceutical
 9 companies, labeling and warnings.” *Bartoli* noted that the *Forman* court had held a
 10 two-day *Daubert* hearing and found that Dr. Parisian’s methodology of reviewing
 11 manufacturer filings, internal documents, and medical literature—“the same
 12 methodology that she applied while working at the FDA”—was a reliable
 13 foundation for her to testify “regarding the reasonableness of Novartis’ conduct in
 14 its interactions with the FDA . . . and interactions with companies regarding
 15 clinical trials.” *Bartoli*, 2014 WL 1515870 at *6 (quoting *Forman*, 794 F. Supp. 2d
 16 at 384; internal quotation marks omitted).

- 17 • *In re Nuvaring Products Liability Litigation*, MDL 1964, 2013 WL 791835, at *4
 18 (E.D. Mo. Mar. 4, 2013), motion to exclude denied in full. The court found Dr.
 19 Parisian’s testimony to be admissible, her methodology reliable, and her opinions
 20 helpful to the jury. Her “opinions, as grounded in credible articles, studies, reports,
 21 and personal experience, are based on a reliable methodology.”

22 Dr. Parisian has employed the same methodology here that she did in the *Xarelto*,
 23 *Jones*, *Ethicon*, *Mirena*, *Block*, *Bartoli*, *Forman*, and *Nuvaring* courts. In those cases and
 24 this one she reviewed the manufacturer’s internal documents, communications between
 25 the manufacturer and the FDA, relevant studies and medical literature, and regulatory
 26 filings. As in those cases, Dr. Parisian uses that foundation to explain to the jury the
 27 significance of those Bard documents as they relate to the larger scheme of FDA’s
 28 regulatory scheme and oversight of IVC filters. And she will further explain how Bard

1 deviated from the applicable FDA regulations and acted inappropriately in continuing to
 2 develop, promote, and sell its line of retrievable IVC filters given what it knew about the
 3 dangers of its products.

4 Bard's citations to the few cases where Dr. Parisian's testimony was stricken in
 5 whole or in part are distinguishable. The court in *In re Trasyol Products Liability*
 6 *Litigation*, No. 08-MD-01928, 2010 WL 1737107 (S.D. Fla. Apr. 27, 2010), excluded Dr.
 7 Parisian from testifying because of concerns that her opinion would be offered by
 8 narrative and would discuss the "intent" of the company.² Several of the other rulings that
 9 excluded her did so because of problems with the specific expert report in those cases.
 10 *See, e.g., Lopez v. I-Flow Inc.*, CV 08-1063-PHX-SRB, 2011 WL 1897548, at *10 (D.
 11 Ariz. Jan. 26, 2011) ("Dr. Parisian's report is a labyrinth that the Court cannot navigate.").
 12 There are no such issues with Dr. Parisian's report in this case, as the *Phillips* court
 13 implicitly held in denying Bard's motion.³ *See also Block*, 937 F. Supp. 2d at 1046
 14 (noting that Dr. Parisian "provided adequate descriptions for the bases for her opinions" in
 15 her report). And she is not being proffered to testify in a narrative form and will not
 16 express any opinions on Bard's intent, motives, or state of mind. Rather, she will follow
 17 the limitations on her testimony imposed by the plethora of other courts that have found
 18 her to be a qualified, helpful, admissible expert witness under Rule 702. The argument
 19 that Dr. Parisian should be excluded based on the older cases cited by Bard rather than the
 20 specifics of the case at issue was best refuted earlier this year by the court in *Jones*:

23 ² Besides the cases denying motions to exclude Dr. Parisian's testimony discussed
 24 above, there are many other cases that have distinguished her adverse case law in denying
 25 motions to exclude. *See, e.g., In re Heparin Product Liability Litigation*, 1:08HC600000,
 26 2011 WL 1059660, at *8 (N.D. Ohio Mar. 21, 2011) (denying motion to exclude Dr.
 27 Parisian, distinguishing *Trasyol* ruling, and citing other cases in accord).

28 ³ Dr. Parisian's report in this MDL is substantively extremely similar to the one
 disclosed in *Phillips*. If anything her MDL report is even further streamlined and
 organized to be straightforward and accessible. Bard's critiques of the report as
 "unwieldy" are conclusory and Bard does not point to any specific structural defects or
 lack of legal authority cited for her opinions.

[T]he overwhelming number of courts who have analyzed Dr. Parisian's qualifications and methodology have allowed her to testify, at least in part. In any event, each court addressing a *Daubert* challenge to an expert, such as this court, must decide the challenge based on its application of relevant law to the facts before it.

235 F. Supp. 3d at 1256; *see also* *Bartoli*, 2014 WL 1515870 at *6 ("Generally, [Dr. Parisian] is qualified to testify.").

B. Dr. Parisian's History of Working for Plaintiffs Can Be Explored by Bard in Cross-Examination at Trial but Is Not an Issue for Rule 702.

Bard critiques Dr. Parisian as a professional plaintiffs' expert, citing her deposition testimony discussing her recent litigation work.⁴ But this is not a valid basis for exclusion. Other than repeating its citations to the negative case law discussed above, Bard offers nothing other than conclusory argument that Dr. Parisian is an "advocate" rather than an expert. Bard does not cite to any specific opinions or testimony demonstrating its claims nor any case law supporting its argument for exclusion based solely on expert bias. *U.S. v. Rincon*, 28 F.3d 921 (9th Cir. 1994), undermines rather than supports Bard on this point. The eyewitness identification expert in that case was excluded not because of bias or because she gave "unfounded and inflammatory opinions"—as Bard falsely claims Dr. Parisian will offer at trial—but because of concerns about the research supporting the expert's opinions and that the expert's testimony would confuse rather than aid the jury. *Id.* at 924-25. Bard has no support for its position that an expert can be excluded under Rule 702 solely because they work more regularly as an expert for one side or the other. Indeed, such a rule would result in the exclusion of almost every defense expert in this case and most other injury and product cases given that the vast majority of defense experts do little if any work for plaintiffs.

⁴ Bard ignores that Dr. Parisian has also worked as a regulatory consultant for industry. *See, e.g.*, Exhibit 3, Deposition of Suzanne Parisian, M.D., June 21, 2017, at 25:14-27:22 (describing work on implantable shunt used to treat Alzheimer's patients). Regardless, these are topics for cross-exam and re-direct examination at trial.

As the *Phillips* court already noted in rejecting Bard’s argument, Bard “may impeach Dr. Parisian as to her bias, but that is a matter separate from her qualifications as an expert.” *Phillips*, 2014 WL 7177256 at *4. Bias, “inflammatory opinions,” and “advocacy” are issues for cross-examination and trial, not motion practice.

C. Dr. Parisian Has Substantial Expertise in the FDA’s Requirements for the Testing and Labeling of Medical Devices.

Next Bard attacks Dr. Parisian’s qualifications to testify and opine upon design, testing, or causation issues. Two of these three areas are obviously outside Dr. Parisian’s area of expertise as a medical doctor, pathologist, and regulatory expert. Dr. Parisian is not an engineer and cannot testify as to alternative designs or design defects in Bard’s IVC filters.⁵ And she is not a medical specialist in areas relevant to causation issues in this case, such as an interventional radiologist, cardiologist, internal medicine doctor, or hematologist.⁶ Plaintiffs thus concede that, to the extent that any opinion offered by Dr. Parisian at trial could be reasonably construed as being an opinion only on “design” or “causation”⁷ that Dr. Parisian will not offer such testimony. Notably—the handful of out-

⁵ There is potentially some commonality between design issues and warning issues that could involve Dr. Parisian’s expertise, however, as at least one court described in denying a motion to exclude Dr. Parisian. *Block*, 937 F. Supp. 2d at 1046 (“The Court notes, however, that there may be some overlap in evidence that applies to a design defect and failure to warn claim because the specifics of a product’s design may lead to the need for particular warnings.”).

⁶ It is conceivable that Dr. Parisian could testify on causation as a pathologist in a case where a defective IVC filter potentially killed the decedent. But that would certainly be specific to an individual case with facts different than any bellwether or other case before the Court at this time.

⁷ Bard’s definition of “causation,” however, appears to be broader than just medical causation i.e., that the IVC filter caused a given Plaintiff’s injuries. Bard cites to Dr. Parisian’s Opinion #2, Defendants’ Exhibit A at 16, as improperly addressing “causation” but this is a straightforward FDA regulatory opinion on the propriety of Bard’s warnings to physicians and recipients of its IVC filters. This has nothing to do with causation and is an area that Dr. Parisian and other FDA experts are well qualified to opine on as numerous courts have held. *See, e.g., In re Ethicon*, 2016 WL 4608165, at *3 (“Dr. Parisian is qualified to testify about product warnings.”).

1 of-context quotes from her report cited by Bard aside—none of Dr. Parisian’s seven
 2 primary opinions in this case remotely touch on design or causation issues.⁸

3 Bard tries to shoehorn “testing” into this argument as well, claiming that Dr.
 4 Parisian is not qualified to opine on medical device testing. This is false. As a physician
 5 and former FDA medical officer Dr. Parisian can explain to the jury the types of studies
 6 the FDA expects device manufacturers to submit to the agency in support of new
 7 indications for use. And as a medical doctor, she is qualified to interpret published
 8 scientific papers and address their significance, particularly the notice they provide to
 9 medical device manufacturers about potential problems with their products. Just because
 10 Dr. Parisian has not specifically tested IVC filters does not render her decades of
 11 experience with studies and testing of medical devices irrelevant. The *Phillips* court so
 12 found, rejecting exactly this argument and holding that Dr. Parisian was qualified to opine
 13 on “industry standards for medical device testing, and whether Defendants complied with
 14 those with respect to the relevant medical devices. . . .” 2014 WL 7177256 at *5. Bard
 15 cites no legal authority for its position that Dr. Parisian cannot opine about whether Bard’s
 16 testing of its IVC filters was adequate for a reasonable medical device manufacturer or
 17 complied with FDA regulations and expectations, and the Court should follow the *Phillips*
 18 court in finding that Dr. Parisian is qualified to do so.

19 **D. Dr. Parisian’s Factual Bases for Her Opinions Are Necessarily and**
 20 **Appropriately Described in Her Report.**

21 This litigation involves 15-year history of the development, testing, regulation, and
 22 sale of multiple iterations of a medical device. Dr. Parisian reviewed a vast amount of
 23 material in researching this history and necessarily crafted long and detailed reports
 24 describing those documents, that history, and all of the bases for her opinions.

25 Bard argues that Dr. Parisian’s reports are too long and that her exhaustive
 26 recitation of the facts and documents in this case constitutes an improper “narrative” such
 27 that she and her report must be excluded. This is a classic, “damned if you do, damned if

28 ⁸ Nor will Dr. Parisian opine on engineering, metallurgy, or corporate ethics.

1 you don't" situation for Plaintiffs and Dr. Parisian. Fed. R. Civ. P. 26 and Fed. R. Evid.
 2 702 both require disclosure of all of the factual information relied on by an expert, and
 3 surely if Dr. Parisian's report were abbreviated Bard would accuse her of failing to lay
 4 foundation for her opinions. But now that she has produced a comprehensive report, it is
 5 allegedly too long and purportedly merely "regurgitates" the facts of the case.⁹

6 Dr. Parisian's proffered testimony is not an impermissible narrative, but rather
 7 helpful testimony for the jury squarely within her realm of expertise. Other courts have
 8 determined that experts like Dr. Parisian may properly testify about, or comment upon,
 9 any document or exhibits in evidence, and may explain "the regulatory context in which
 10 they were created, defining any complex or specialized terminology or drawing inferences
 11 that would not be apparent without the benefit of experience or specialized knowledge."
 12 *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y.2009). Thus, the
 13 factual materials considered by Dr. Parisian are not intended to be the subject of her
 14 testimony in and of themselves. Rather, the documents, evidence and factual matters
 15 referenced form the basis of her opinion and are relevant and helpful to the jury in
 16 explaining the regulatory context in which they were created. Her descriptions illustrate
 17 the considerations that are relevant at different stages of the regulatory process, and allow
 18 Dr. Parisian to apply her expertise to draw inferences that would not otherwise be
 19 apparent to the jury. The use of factual materials in this way does not violate the rule
 20 against factual narratives. *Id.*

21 Courts have noted that the objection to an expert's testimony as a factual narrative
 22 is better made at trial because the "appropriate solution" is not to "parse the expert's
 23

24 ⁹ Bard acknowledges that its own experts likewise include a description of the
 25 regulatory history of Bard's IVC filters in their own Rule 26 reports. But of course *those*
 26 reports are totally different from Dr. Parisian's; Bard's expert reports "provide substantive
 27 regulatory analysis that would actually be helpful to the jury," reference only documents
 28 Bard has determined are appropriate, and in Bard's estimation more properly link its
 experts' opinions to the experts' factual descriptions. Bard offers no examples or citations
 to support its conclusion that Dr. Parisian's report is impermissible narrative when its own
 experts' reports follow the same format.

report” but, rather, to trust both that plaintiffs’ counsel will only present the facts necessary to the expert’s opinion and that the Court will be able to cut off any lengthy factual narratives. *In re C.R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, 948 F. Supp. 2d 589, 645-646 (S.D. W. Va. 2013) (quoting *Liberty Media Corp. v. Vivendi Universal, S.A.*, 874 F. Supp. 2d 169, 174 (S.D.N.Y. 2012)); accord *Staub v. Breg, Inc.*, 2012 WL 1078335 *3 (D. Ariz., Mar. 30, 2012) (“Objections to narrative testimony are best made at trial.”). Bard also argues for broad exclusion of Dr. Parisian and her opinions based on her “selectively quoting” documents provided by Plaintiffs’ counsel. But this too is a trial objection, not a *Daubert*/Rule 702 issue. *In re Nuvaring*, 2013 WL 791835 at *4 (“As to cherry picking data, the Eighth Circuit has recently made clear that such allegations should be left for cross-examination. See *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 633 (8th Cir.2012).”).

Bard cites to a 2008 ruling in *In re Prempro* where the Eighth Circuit was critical of Dr. Parisian providing narrative testimony on the stand. *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009). But how Dr. Parisian testified in a single case almost a decade ago has nothing to do with excluding her as an expert now. The many cases since then approving her as an expert witness—including the *Phillips* court allowing her to testify against Bard about the dangers of its IVC filters—demonstrate that she is a helpful and well-qualified witness. See *Jones*, 235 F. Supp. 3d at 1256–57 (acknowledging *In re Prempro* and noting that while it may guide courts to monitor Dr. Parisian’s direct examination for narrative testimony it does not support excluding her in full). Bard’s objections to narrative testimony are for trial.

E. Opinions That Bard Did Not Follow FDA Regulations and Federal Law Are Not Legal Conclusions on Ultimate Issues of Law.

The argument that Dr. Parisian improperly opines on ultimate issues of law fails because Plaintiffs’ claims are not that Bard violated FDA regulations but that they designed and marketed a defective product. Bard’s violations of FDA regulations as described by Dr. Parisian are merely evidence of Bard’s failure to appropriately warn

1 doctors and the public or that its IVC filters were defectively designed. Bard seeks to
2 conflate the two concepts to manufacture an argument that Dr. Parisian's legal
3 conclusions—to the extent her opinions on Bard's compliance with FDA regulations can
4 be characterized as such—are on ultimate issues, but this is not a fraud-on-the-FDA or
5 FDA regulation violation case, it is a product liability and negligence case.

6 As with many of Bard's arguments, this attack on Dr. Parisian was already denied
7 in *Phillips*, which found that her legal conclusions were not on ultimate issues but rather
8 were relevant to several issues in the case and thus admissible:

9 The Court disagrees that Dr. Parisian's conclusions that Defendants violated
10 this or that regulation amount to legal conclusions on ultimate issues.
11 Defendants are not charged in the present case with violations of any
12 regulations. Their alleged violations of regulations are merely relevant to
13 whether they satisfied the standard of care. Violation of a regulation can in
14 some cases result in a finding of negligence per se. At a minimum, it is
15 relevant to the issue of negligence, and experts may testify as to industry
16 standards. In this case, it appears that Dr. Parisian will testify as to FDA
regulations for testing based on her particular experience in this area, and
whether Defendants violated them with respect to the medical devices at
issue.

17 *Phillips*, 2014 WL 7177256 at *4; *see also Staub*, 2012 WL 1078335 at *3 (“Plaintiffs are
18 not offering [their regulatory expert] as an expert on the ultimate issues of law in this case.
19 Her testimony regarding FDA regulations could be helpful to the jury and will not usurp
20 its role of deciding whether defendant violated Arizona law.”); *In re Mirena*, 169 F. Supp.
21 3d at 479 (“Moreover, because this case involves state law claims of negligence and strict
22 liability, Dr. Parisian's testimony regarding compliance with FDA regulations does not
23 usurp the role of the jury, but rather merely helps them understand a complicated statutory
24 framework.” (citing *In re Fosamax*, 645 F. Supp. 2d at 191 n.16.)). Dr. Parisian's
25 conclusions about Bard's compliance with federal law and regulations do not address
26 ultimate issues of law and are thus admissible.

F. Dr. Parisian’s Discussion of What Bard “Knew” and Similar Comments Are Based on Documents and Undisputed Facts, Not Speculation.

Dr. Parisian’s opinions about what Bard “knew” and what other entities knew or intended are based on facts, not speculation or conclusions. Whether talking about what Bard knew internally, such as that its line of retrievable IVC filters did not have the same safety profile as permanent filters, or why the FDA took the actions it did, or even what the intent of the SIR Guidelines are, Dr. Parisian relies on the record. There is nothing improper about her citing to the actual underlying documents in forming her opinions, nor is this improper “mens rea” testimony.¹⁰ Taking Bard’s examples one by one:

- Dr. Parisian extensively cites in her report all of the evidence that Bard was internally aware that its retrievable filters were having higher complication rates than its permanent filter, the Simon Nitinol Filter (SNF). *See* Defendants’ Exhibit A, at 36-37 (citing 15 different internal Bard studies and assessments as “examples of information Bard had prior to 510(k) clearance which should have supported that the SNF and [Recovery filter] were not substantially equivalent” when implanted in patients as a permanent device). Saying that Bard knew of these problems with its IVC filters and that they were worse than the complications rates with the SNF is fact, not speculation. Similarly, in her MDL deposition Dr. Parisian testified that Bard was aware of an issue with the Meridian filter that she had discussed in her supplemental report where “the weld characterization of one wrist anchor did not support the 5lb load.” *See* Defendants’ Exhibit B, at 15, ¶ 20. This is based entirely on an internal Bard testing analysis of the Meridian; she is almost literally quoting Bard’s report. *See* Exhibit 4, Diaphragmatic Flat Plate Fatigue and Corrosion Examination of the Meridian Filter, BPVEFILTER-01-01780607, at 8 of 12 (“However, during the weld characterization, one wrist anchor did not support the 5.0 lb proof load.”). It would be illogical and certainly

¹⁰ Plaintiffs acknowledge that Dr. Parisian cannot testify about what Bard “intended” and will not offer any such testimony from her at trial.

confusing to the jury for Dr. Parisian not to describe Bard as “knowing” about an issue that it documented in its own report.

- Dr. Parisian’s discussions in her reports of the FDA’s thoughts, intentions, or plans, which are very limited, are based entirely on the text of the communications back-and-forth between the FDA and Bard. Bard’s cited example is Dr. Parisian’s description of a February 10, 2000, meeting between the two groups based on Bard correspondence with the FDA about the topics for discussion at the meeting and information that Bard was trying to provide to the FDA on certain topics at the FDA’s request. *See* Defendants’ Exhibit A, ¶ 154 at 60 (describing contents of November 1, 1999, and January 20, 2000, letters from Nitinol Medical Technologies to the FDA describing filter issues for discussion at February 10, 2000, meeting). Again, this is not speculation or improper “mens rea” opinion, this is just accurately stating the regulatory history of Bard’s IVC filters based on the documentation of that history.
- The SIR Guidelines themselves disclaim any intention that they be used as quality assurance rules. The bold, all-caps “SIR Disclaimer” at the end of the document states, “The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. *These guidelines are voluntary and are not rules.*” Exhibit 5, Caplin, et al., *Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism*, 22 J. Vasc. Interv. Radiol. 1499, 1506 (2011) (emphasis added).

Discussing the SIR Guidelines and communications from the FDA without talking about what they expressly say would be absurd. And as for Bard’s internal documents, when studies and reviews are being conducted by Bard, and the conclusions of those studies and reviews are disseminated within Bard, it is proper to say that Bard “knew” about the results of the studies. There is nothing improper about such testimony.

G. Dr. Parisian Is Not Testifying as a “Scientist” Therefore Her Testimony Based on Her Expertise with the FDA and the Methodology She Used There Is Appropriate.

Bard argues Dr. Parisian must be excluded because she has not applied scientific rigor to her opinions. The Court has previously acknowledged in a medical device case that this argument has been rejected by the Ninth Circuit:

The process of obtaining FDA approvals and applying FDA regulations is not subject to mathematical measurements or laboratory analyses. [Plaintiffs’ FDA expert] does not purport to have applied scientific formulas or testing methods that are subject to laboratory verification or peer review. Her testimony is based on analysis of the facts she considers relevant in light of her years of experience and training. As the Ninth Circuit has noted, “[t]he *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable to this kind of testimony, whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.” *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000).

Placencia, 2012 WL 5877624 at *10. The *Phillips* court held similarly in admitting Dr. Parisian’s testimony; “[a]s to the areas in which the Court is likely to admit Dr. Parisian, i.e., governmental regulations and perhaps the appropriateness of testing as to a given device, no detailed scientific methods would be expected.” 2014 WL 7177256 at *5. Other courts in medical device multi-district litigations have likewise rejected Bard’s argument. *In re Mirena*, 169 F. Supp. 3d at 480 (“None of the four factors listed in *Daubert* apply to Dr. Parisian, which makes sense because she is not purporting to be a scientist giving a scientific opinion.”); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL 2327, 2014 WL 186872, at *18 (S.D.W. Va. Jan. 15, 2014) (admitting plaintiffs’ regulatory expert based on her background despite fact she was not a “doctor or biomedical engineer”).

Dr. Parisian reviewed extensive documentation of the regulatory history of Bard’s IVC filters as well as materials obtained in this litigation in arriving at her opinions. *See* Defendants’ Exhibit A, at 8-15 (docs reviewed list). Her methodology—which is

1 accurately described in the deposition testimony from *Phillips* quoted in Bard's motion—
 2 is logical, based on her experience with the FDA, and as described above has been
 3 approved by the many courts that have admitted her as an expert. Neither of the two
 4 Ninth Circuit cases cited by Bard for support, *Cabrera v. Cordis Corp.*, 134 F.3d 1418
 5 (9th Cir. 1998), and *Guidroz-Brault v. Missouri Pacific Railway Co.*, 254 F.3d 825 (9th
 6 Cir. 2001), involved regulatory experts like Dr. Parisian. There is nothing supporting
 7 excluding her based on her methodology, other than the same handful of old rulings
 8 against her which are dated outliers as explained above.

9 **H. Testimony by FDA Regulatory Experts Like Dr. Parisian in Medical**
 10 **Device Litigation Is Not Preempted.**

11 Bard makes a brief argument that Dr. Parisian's testimony must be excluded
 12 because it is preempted by *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).
 13 This argument is addressed in more detail in Plaintiffs' response to Bard's motion to
 14 excluded Dr. David Kessler, Plaintiffs' other FDA regulatory expert, and those arguments
 15 are incorporated herein by reference. But to be clear, Plaintiffs are not making a claim of
 16 fraud on the FDA, or that Bard violated an "FDA standard of care." *See Block*, 937 F.
 17 Supp. 2d at 1046. Thus *Buckman* does not apply. *See In re Yasmin & YAZ*
 18 *(Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH,
 19 2011 WL 6302287, at *11 (S.D. Ill. Dec. 16, 2011) (noting in defective drug litigation the
 20 plain distinction between *Buckman*, which involved claim preemption, and plaintiffs'
 21 failure to warn case that did not assert a "fraud on the FDA" claim; "there is no way to
 22 analyze *Buckman* to have any impact on this case"). Bard made this exact same argument
 23 as to Dr. Kessler in the litigation over its transvaginal mesh products and lost. *In re C.R.*
 24 *Bard, Inc., Pelvic Repair Sys.*, 948 F. Supp. 2d at 630 (holding that Dr. Kessler was
 25 permitted to testify that Bard "did not disclose certain information to the FDA that
 26 Dr. Kessler . . . would have found pertinent."); *see also In re Yasmin*, 2011 WL 6302287,
 27 at *11 (holding that *Wyeth v. Levine*, 555 U.S. 555 (2009), "made clear . . . that federal
 28 law does not prevent judges and juries in failure to warn cases from considering a drug

1 companies [sic] compliance with FDA regulations.”); *In re Vioxx Prods. Liab. Litig.*, 401
2 F. Supp. 2d 565, 587 (E.D. La. 2005) (holding in defective drug litigation that *Buckman*’s
3 holding was limited to state law fraud-on-the-FDA cases, which rendered it “completely
4 inapplicable to the issue at hand”). Preemption does not prevent FDA expert testimony.

5 **V. CONCLUSION**

6 Based on the foregoing reasons, Plaintiffs respectfully request that the Court deny
7 in full Bard’s Motion to Exclude Dr. Parisian.

8 RESPECTFULLY SUBMITTED this 27th day of September, 2017.

9
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21 **CERTIFICATE OF SERVICE**

22 I hereby certify that on this 27th day of September, 2017, I electronically
23 transmitted the attached document to the Clerk’s Office using the CM/ECF System for
24 filing and transmittal of a Notice of Electronic Filing.

25 /s/ Gay Mennuti
26
27
28